

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

Dr. Paul Teirstein,

Plaintiff,

vs.

AGA Medical Corporation,

Defendant.

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Civil Action No. 6:08-CV-00014-LED

**DEFENDANT AGA MEDICAL CORPORATION'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant AGA Medical Corporation (“AGA”), by and through its undersigned counsel, hereby submits this Answer, Affirmative Defenses, and Counterclaims (“Answer”) in response to the Complaint of Plaintiff Dr. Paul Teirstein (“Teirstein”). Except to the extent expressly admitted herein, AGA denies each and every allegation in the Complaint. The numbered paragraphs in the Answer correspond to the numbered paragraphs of the Complaint.

PARTIES

1. AGA lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Complaint, and, therefore, denies those allegations.

2. AGA admits that it is a Minnesota corporation, organized under the laws of the State of Minnesota, with its principal place of business located at 5050 Nathan Lane North, Plymouth, Minnesota, 55442.

VENUE AND JURISDICTION

3. The allegations contained in paragraph 3 of the Complaint consist of Teirstein's characterization as to the nature of the action and the basis for invoking the jurisdiction of this Court and contain no factual allegations to which a response is required.

4. AGA admits only that it conducts business in the Eastern District of Texas and that this Court has personal jurisdiction over AGA. Otherwise, AGA denies the allegations contained in paragraph 4 of the Complaint.

5. AGA admits only that it conducts business in the Eastern District of Texas, that it is subject to personal jurisdiction in the Eastern District of Texas, and that venue is proper in the Eastern District of Texas. Otherwise, AGA denies the allegations contained in paragraph 5 of the Complaint.

ACTS GIVING RISE TO THE COMPLAINT

6. AGA denies the allegations contained in the first and second sentences of paragraph 6 of the Complaint. AGA denies the allegations contained in the last sentence of paragraph 6 of the Complaint to the extent that it alleges that Teirstein invented an invention. Otherwise, AGA lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 6 of the Complaint, and, therefore, denies those allegations.

7. AGA denies that U.S. Patent No. 5,499,995 (the "'995 patent'") was "duly and legally issued." AGA admits that a purported copy of the '955 patent is attached to the Complaint as Exhibit A.

8. AGA lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 8 of the Complaint, and, therefore, denies those allegations.

9. AGA lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 9 of the Complaint, and, therefore, denies those allegations.

10. AGA admits only that a reexamination certificate issued for the '995 patent on March 12, 2002, which certificate speaks for itself. Otherwise, AGA denies the allegations contained in paragraph 10 of the Complaint.

11. AGA admits that it manufactures occluding devices and accessories for occluding devices in the United States and that it sells such devices in the United States and elsewhere, including the Septal Occluder, the Multi-Fenestrated Septal Occluder, the PFO Occluder, the Membranous VSD Occluder, the Vascular Plug, the Vascular Plug II, the Duct Occluder, the Muscular VSD Occluder, and the P.I. Muscular VSD Occluder. AGA admits that pictures of some of the devices manufactured by AGA are attached to the Complaint as Exhibits B, C, D, and E.

12. AGA admits only that it has not entered into any licensing agreement with Teirstein regarding the '995 patent. AGA lacks knowledge or information sufficient to form a belief as to the truth of the allegation that Teirstein has not received any financial benefit from devices manufactured by AGA, and, therefore, denies any such allegation. Otherwise, AGA denies the allegations contained in paragraph 12 of the Complaint.

13. AGA admits that, on November 2, 2004, Mr. Gougeon and Mr. Borg received an email from Teirstein seeking to license the '995 patent and stating that Teirstein and his attorneys believed that some of AGA's devices infringed claims 7, 12, 21, 27, and 36 of the '995 patent. AGA admits that Mr. Gougeon was an employee of AGA on November 2, 2004. AGA denies the allegation that Mr. Borg was an employee of AGA on November 2, 2004.

14. AGA admits that Teirstein and/or his attorneys sent more than one letter to AGA and/or its attorneys alleging infringement of the '995 patent, and that AGA and/or its attorneys sent more than one letter to Teirstein and/or his attorneys apprising Teirstein of the specific reasons why Teirstein's allegations of infringement were baseless. Upon information and belief, AGA and/or its attorneys responded to all of the letters received from Teirstein and/or his attorneys alleging infringement of the '995 patent. Upon information and belief, the last communication to or from Teirstein and/or his attorneys regarding the '995 patent was a letter dated August 23, 2006, sent by AGA's attorneys to Teirstein's attorneys, which maintained that Teirstein's allegations of infringement were baseless and that AGA would seek costs, attorneys' fees, and any other available sanctions if required to defend against Teirstein's baseless allegations in court. AGA admits that it has not entered into any agreement with Teirstein regarding the '995 patent. AGA lacks knowledge or information sufficient to form a belief as to the truth of the allegation that Teirstein contacted AGA in hopes of reaching an amicable agreement, and, therefore, denies those allegations.

15. AGA admits only that, subsequent to the email sent by Teirstein to Mr. Gougeon and Mr. Borg on November 2, 2004, AGA received FDA authorization for and began selling one or more occluding devices. Otherwise, AGA denies the allegations contained in paragraph 15 of the Complaint.

CLAIMS FOR RELIEF

COUNT ONE **INFRINGEMENT OF THE '995 PATENT**

16. AGA incorporates by reference its responses to the allegations contained in paragraphs 1 through 15, as if fully set forth herein.

17. AGA denies the allegations contained in paragraph 17 of the Complaint.

18. AGA denies the allegations contained in paragraph 18 of the Complaint.

19. AGA denies the allegations contained in paragraph 19 of the Complaint.

20. AGA denies the allegations contained in paragraph 20 of the Complaint.

21. AGA denies the allegations contained in paragraph 21 of the Complaint.

22. AGA denies the allegations contained in paragraph 22 of the Complaint.

23. AGA admits only that this case is exceptional in that AGA is entitled to such a finding in its favor and is entitled to an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285, as Teirstein's infringement allegations are without merit and could not have been the product of an adequate investigation. AGA denies the allegation contained in paragraph 23 of the Complaint that Teirstein is entitled to an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

24. AGA denies the allegations contained in paragraph 24 of the Complaint.

PRAYER FOR RELIEF

Teirstein is not entitled to any of the relief sought in the Prayer for Relief of the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

1. The claims of the '995 patent are invalid and void for failing to satisfy one or more provisions of the patent laws of the United States, 35 U.S.C. §§ 101 *et seq.*, including, but not limited to, the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

SECOND AFFIRMATIVE DEFENSE

2. Teirstein's claims against AGA are barred, in whole or in part, by the doctrine of prosecution history estoppel.

THIRD AFFIRMATIVE DEFENSE

3. Teirstein's claims against AGA are barred, in whole or in part, by one or more of the doctrines of laches and/or equitable estoppel.

FOURTH AFFIRMATIVE DEFENSE

4. Teirstein is barred from recovering damages, in whole or in part, by 35 U.S.C. § 287.

FIFTH AFFIRMATIVE DEFENSE

5. The '995 patent is unenforceable as a result of inequitable conduct arising from material misrepresentations that Teirstein made to the U.S. Patent and Trademark Office ("PTO"), with the intent to deceive the PTO. During the reexamination of the '995 patent, Teirstein, through his attorney, submitted a document entitled "Patent Owner's Statement" to the PTO, which purported to distinguish the claims of the '995 patent from a new prior art reference, U.S. Patent No. 5,382,261 to Palmaz (the "'261 patent"). In the Patent Owner's Statement, Teirstein represented to the PTO that claims 7 and 12 of the '995 patent were patentable over the '261 patent, because claims 7 and 12 recite a frame having a mesh structure, whereas the stent

disclosed in the '261 patent could not be characterized as having a mesh structure. However, the specification of the '261 patent incorporates by reference U.S. Patent No. 4,733,665 to Palmaz (the "'665 patent"). The specification of the '665 patent, which is thus legally part of the '261 patent, expressly discloses a stent having a mesh structure. Both Teirstein and his attorney were aware of the '665 patent, having made reference to it elsewhere in the Patent Owner's Statement. Therefore, upon information and belief, Teirstein made a material misrepresentation regarding the '261 patent to the PTO with the intent to deceive the PTO. Further, Teirstein also, in a separate instance, misrepresented the '665 patent. Specifically, Teirstein, through his attorney, represented to the PTO (in the same Patent Owner's Statement) that the stent disclosed in the '261 patent is "identical" to the stent disclosed in the '665 patent. As discussed above, Teirstein had already falsely represented to the PTO that the '261 patent does not disclose a stent with a mesh structure. Thus, by asserting that the stent of the '261 patent is "identical" to that of the '665 patent, Teirstein also falsely represented to the PTO that the stent of the '665 patent does not have a mesh structure (when, in fact, it expressly does). Therefore, upon information and belief, Teirstein made a material misrepresentation regarding the '665 patent to the PTO with the intent to deceive the PTO.

COUNTERCLAIMS

For its counterclaims, AGA alleges, upon personal knowledge as to its own actions and upon information and belief as to the actions of Teirstein, as follows:

NATURE OF THE ACTION

1. This is a civil action arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, for a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 that U.S. Patent No. 5,499,995 (the “‘995 patent”) has not been infringed by AGA and that the ‘995 patent is invalid and unenforceable.

2. AGA re-alleges and incorporates herein by reference the allegations, denials, and Affirmative Defenses contained in its Answer as if fully set forth herein.

PARTIES

3. AGA is a Minnesota corporation with its principal place of business located at 5050 Nathan Lane North, Plymouth, Minnesota, 55442.

4. Upon information and belief, Teirstein is a resident of California.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Personal jurisdiction over Teirstein is proper based on the commencement of this action.

7. Venue for AGA’s counterclaims is properly laid in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

COUNTERCLAIM I
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE '995 PATENT

8. AGA incorporates herein by reference the allegations in its Affirmative Defenses and in paragraphs 1-7 above.

9. This counterclaim is for a declaratory judgment relating to the '995 patent.

10. This counterclaim arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and a case of actual controversy exists within the jurisdiction of this Court.

11. Teirstein has brought an infringement suit against AGA wrongfully alleging that AGA's products infringe and will continue to infringe the '995 patent.

12. AGA's products have not infringed, and do not infringe any claim of the '995 patent, either literally or under the doctrine of equivalents and do not infringe either directly or under the theory of inducement or contributory infringement.

13. There is a justiciable controversy between Teirstein and AGA as to the matters asserted herein regarding the '995 patent.

14. AGA is entitled to a declaratory judgment that the claims of the '995 patent have not been, and are not being, infringed.

COUNTERCLAIM II
DECLARATORY JUDGMENT OF
INVALIDITY OF THE '995 PATENT

15. AGA incorporates herein by reference the allegations in its Affirmative Defenses and in paragraphs 1-14 above.

16. This counterclaim is for a declaratory judgment relating to the '995 patent.

17. This counterclaim arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and a case of actual controversy exists within the jurisdiction of this Court.

18. Teirstein has brought an infringement suit against AGA wrongfully alleging that AGA's products infringe and will continue to infringe the '995 patent.

19. The claims of the '995 patent are invalid for failing to satisfy one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

20. There is a justiciable controversy between Teirstein and AGA as to the matters asserted herein regarding the '995 patent.

21. AGA is entitled to a declaratory judgment that the claims of the '995 patent are invalid.

COUNTERCLAIM III
DECLARATORY JUDGMENT OF
UNENFORCEABILITY OF THE '995 PATENT
ARISING FROM INEQUITABLE CONDUCT

22. AGA incorporates herein by reference the allegations in its Affirmative Defenses and in paragraphs 1-21 above.

23. This counterclaim is for a declaratory judgment relating to the '995 patent.

24. This counterclaim arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and a case of actual controversy exists within the jurisdiction of this Court.

25. Teirstein has brought an infringement suit against AGA wrongfully alleging that AGA's products infringe and will continue to infringe the '995 patent.

26. The '995 patent is unenforceable as a result of inequitable conduct arising from material misrepresentations that Teirstein made to the PTO, with the intent to deceive the PTO.

During the reexamination of the '995 patent, Teirstein, through his attorney, submitted a document entitled "Patent Owner's Statement" to the PTO, which purported to distinguish the claims of the '995 patent from a new prior art reference, the '261 patent. In the Patent Owner's Statement, Teirstein represented to the PTO that claims 7 and 12 of the '995 patent were patentable over the '261 patent, because claims 7 and 12 recite a frame having a mesh structure, whereas the stent disclosed in the '261 patent could not be characterized as having a mesh structure. However, the specification of the '261 patent incorporates by reference the '665 patent. The specification of the '665 patent, which is thus legally part of the '261 patent, expressly discloses a stent having a mesh structure. Both Teirstein and his attorney were aware of the '665 patent, having made reference to it elsewhere in the Patent Owner's Statement. Therefore, upon information and belief, Teirstein made a material misrepresentation regarding the '261 patent to the PTO with the intent to deceive the PTO. Further, Teirstein also, in a separate instance, misrepresented the '665 patent. Specifically, Teirstein, through his attorney, represented to the PTO (in the same Patent Owner's Statement) that the stent disclosed in the '261 patent is "identical" to the stent disclosed in the '665 patent. As discussed above, Teirstein had already falsely represented to the PTO that the '261 patent does not disclose a stent with a mesh structure. Thus, by asserting that the stent of the '261 patent is "identical" to that of the '665 patent, Teirstein also falsely represented to the PTO that the stent of the '665 patent does not have a mesh structure (when, in fact, it expressly does). Therefore, upon information and belief, Teirstein made a material misrepresentation regarding the '665 patent to the PTO with the intent to deceive the PTO.

27. There is a justiciable controversy between Teirstein and AGA as to the matters asserted herein regarding the '995 patent.

28. AGA is entitled to a declaratory judgment that the '995 patent is unenforceable.

PRAYER FOR RELIEF

WHEREFORE, counterclaimant AGA requests that this Court:

- A. Enter an Order dismissing Plaintiff/Counter-Defendant Teirstein's Complaint in its entirety with prejudice;
- B. Enter a Declaratory Judgment in favor of AGA and against Teirstein to the effect that AGA has not infringed and is not infringing U.S. Patent No. 5,499,995;
- C. Enter a Declaratory Judgment in favor of AGA and against Teirstein declaring that the claims of U.S. Patent No. 5,499,995 are invalid;
- D. Enter a Declaratory Judgment in favor of AGA and against Teirstein declaring that U.S. Patent No. 5,499,995 is unenforceable;
- E. Award AGA its costs in defending Teirstein's claims;
- F. Enter an Order deeming this case exceptional and awarding AGA its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and
- G. Award AGA such other and further relief as the Court may deem just and appropriate.

Dated: February 11, 2008

Respectfully submitted,

/s/ John M. Pickett

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this motion was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed.R.Civ.P.5(d) and Local Rule CV-5(e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy via facsimile and/or U.S. First Class Mail this 11th day of February, 2008.

/s/ John M. Pickett
John M. Pickett